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Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

Section a):

1. Submitter: Tetrad Corp.
   357 Inverness Dr. S. Suite A
   Englewood, CO 80112
   Contact Person: Dennis R. Dietz Ph.D.
   Chief Technical Officer, Manager Regulatory Affairs
   Telephone: 303-754-2320; Fax: 303-754-2329
2. Date Prepared: June 7, 2000
3. Device Name: Tetrad TC-C3-ACP General Purpose Imaging Probe
   R 892.1570, 90-ITX
4. Marketed Device: Tetrad TC-C3-ACP General Purpose Imaging Probe
5. Device Description: The Tetrad TC-C3-ACP General Purpose Imaging Probe is a replacement part for the Acuson C3 Probe used on the XP128 and Aspen products.
6. Indications for Use: The Tetrad TC-C3-ACP probe is intended for use by a qualified physician for ultrasound evaluation of abdominal organs and for fetal exams.
7. Comparison with Predicate Device: The Tetrad TC-C3-ACP is substantially equivalent to the Acuson C3 General Purpose Imaging Probe. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same array parameter design, and has the same intended uses, operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. Clinical Tests: None required.
3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Tetrad Corporation that the Tetrad TC-C3-ACP probe is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Dennis R. Dietz, Ph.D.
Chief Technical Officer
Tetrad Corporation
357 Inverness Dr. S., Suite A
ENGLEWOOD CO 80112

Re: K002193
Trade Name: Tetrad TC-C3-ACP Ultrasound Probe
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: March 13, 2001
Received: March 15, 2001

Dear Dr. Dietz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson 128XP and Aspen Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number
TC-C3-ACP

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

APPENDIX E Diagnostic Ultrasound Indications for Use Form

Tetrad TC-C3-ACP used on Acuson 128XP and Aspen

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N[1]	N[1]	N[1,2]	N[1,2]	N[1,2]	N[1,2]	N[1,2]	B/CD/M; PW/CW	
Abdominal		N[1]	N[1]	N[1,3]	N[1,3]	N[1,3]	N[1,3]	N[1,3]	B/CD/M; PW/CW	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis. Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M, Combined includes B/M, B/Color M, B/PWD, B/Color/PWD.

Note 1: These indications for use have been approved for the Acuson C3, the probe for which this is a functionally similar probe.
Note 2: Fetal Doppler is not indicated for use in Track 1
Note 3: Abdominal Doppler does not include fetal Doppler in Track 1

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002193